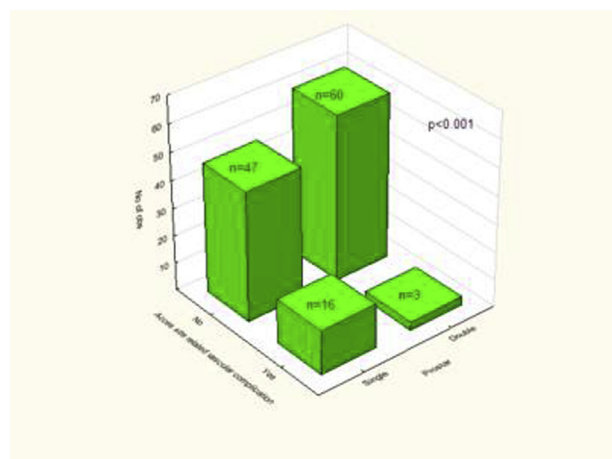


Results: Patients were aged 83 ± 6 years, 50% were male, with a log EuroSCORE II 8 ± 5.8 and 82% being in NYHA class III or IV. The CoreValve aortic valve prosthesis was used in all patients, and all procedures were done without general anesthesia. No differences were found between SP and DP group in clinical and procedural characteristics. Primary endpoint occurred in 25% ($n=16$) of the SP patients and in 5% ($n=3$) of DP patients ($p < 0.001$) (Figure). Postprocedure Hb-fall was $20.0 \text{ g/L} (\pm 13)$ in the SP and $14.3 \text{ g/L} (\pm 8)$ in the DP group ($p < 0.005$).



Conclusions: The double Prostar XL large arterial closure technique during TAVI was associated with less access-site related vascular complication and less blood loss compared with single Prostar XL.

TCT-784

Alternative Applications of a Novel Hybrid Closure Technique in Large Bore Arteriotomies—Uses in Transfemoral Transcatheter Aortic Valve Replacement and the Axillary Artery

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Background: We have previously demonstrated the safety and efficacy of our hybrid closure (HC) technique which employs the combination of 1 “pre-closed” Perclose (P) suture mediated vascular closure device (VCD) followed by the deployment of a 6 French (Fr) Mynx or 6 Fr Angioseal to effect hemostasis in up to 14 Fr arteriotomies (AR) in patients undergoing high risk coronary intervention with Impella 2.5 or CP support via the common femoral artery (CFA). We further sought to determine if this method could also reliably achieve hemostasis in the setting of transfemoral (TF) transcatheter aortic valve replacement (TAVR) utilizing an expandable sheath (e-sheath) with an outer diameter of 16Fr and in the setting of the use of alternate large bore AR sites, namely the axillary artery (AA).

Methods: 4 patients undergoing TF-TAVR and 1 patient undergoing high risk PCI with Impella 2.5 support inserted via the left axillary artery (AA) due to severe peripheral vascular disease had their large bore AR closed in the following manner. Post-procedure, the 16 Fr e-sheath or 13 Fr Impella sheath was removed and a 0.035” wire was inserted into the vessel through the sheath. As the sheath was withdrawn the vessel was “partially pre-closed” with 1 P device. For the 16 Fr AR, an 8 Fr sheath was advanced over the 0.035 wire achieving temporary hemostasis, and effectively reducing a 16Fr to a 8Fr AR site. The 8Fr AR site was then simply closed with an 8 Fr Angioseal vascular closure device. For the 13 Fr AR in the left AA a 6 Fr sheath was inserted after deployment of the P and a 6 Fr sheath and angioseal VCD used. Angiograms of all AR sites were performed after HC. Follow up was done the next day and at 30 days.

Results: Hybrid closure was successful in achieving complete hemostasis in all 4 TF-TAVR cases and in the high-risk Impella supported PCI via the left AA. All patients who underwent HC were free of complications at day 1 and 30 post-procedure.

Conclusions: HC is a simple and safe alternative to the traditional “pre-close” technique. HC is also reliable in effecting hemostasis in patients undergoing TF-TAVR and in closure of large bore AR of the AA. Larger studies are needed to validate our findings.

TCT-785

Comparison of 30-day Major Vascular Complications between Transfemoral and Transapical Accesses in Transcatheter Aortic Valve Replacement: an Updated Meta-Analysis using Standardized Definitions

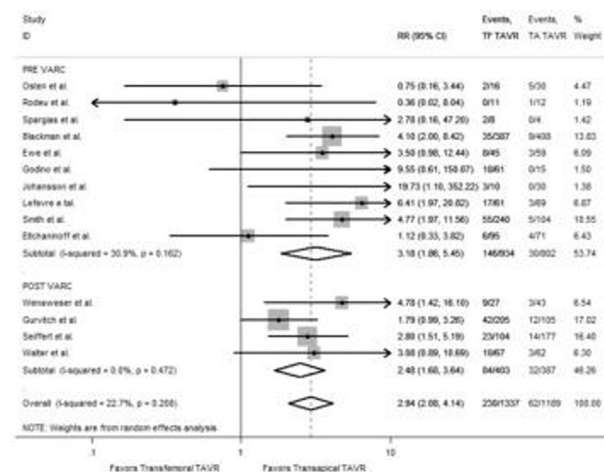
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Background: Direct comparison of transfemoral (TF) and transapical (TA) accesses for Transcatheter Aortic Valve Replacement (TAVR) is troublesome due to heterogeneity in outcome definitions between studies. We used applied standardized Valve Academic Research Consortium (VARC) definition of vascular complications to perform an updated meta-analysis for patients receiving Edwards SAPIEN TAVR via TF and TA approaches.

Methods: Pubmed and Scopus databases were searched for studies that compared the incidence of major vascular complications in TF and TA accesses in Edwards SAPIEN TAVR procedures. Random-effects model was used to calculate the relative risk. Heterogeneity was assessed with Higgins and Thompson I² statistic. All analyses were performed using STATA 11.2 (Texas, USA).

Results: Fourteen studies met all inclusion criteria. A total of 2,526 patients were included, of which 1,337 (52.9%) had TF TAVR. As illustrated in figure 1, the pooled risk of major vascular complications with the TF access was significantly higher than the TA approach (17.2% x 5.2%, respectively; RR 2.94, 95% CI 2.08-4.14). This difference was consistent among studies that predated VARC criteria (RR 3.18, 95% CI 1.86-5.45) and those that adopted VARC standardized outcome definitions (RR 2.48; 95% CI 1.68-3.64).



Conclusions: In this updated meta-analysis, TF access was associated with a significantly higher incidence of 30-day major vascular complications when compared to the TA technique. This difference persisted in studies that used standardized VARC definitions.